

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-19-0023; NOP-19-01]

RIN 0581 AD83

National Organic Program; Proposed Amendments to the National List of Allowed and Prohibited Substances per October 2018 NOSB Recommendations (Crops and Handling)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the National List of Allowed and Prohibited Substances (National List) section of the United States Department of Agriculture's (USDA's) organic regulations to implement recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB). This rule proposes to add blood meal, made with sodium citrate, to the National List as a soil fertilizer in organic crop production; add natamycin to the National List to prohibit its use in organic crop production; and add tamarind seed gum as a non-organic agricultural substance for use in organic handling when organic forms of tamarind seed gum are not commercially available.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Interested persons may comment on the proposed rule using the following procedures:

<u>Federal eRulemaking Portal</u>: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Robert Pooler, Standards Division, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW, Room 2642-S., Ag Stop 0268, Washington, DC 20250-0268. Telephone: (202) 720-3252.

Instructions: All submissions received must include the docket number AMS-NOP-19-0023, NOP-19-01, and/or Regulatory Information Number (RIN) 0581-AD83 for this rulemaking. When submitting a comment, clearly indicate the proposed rule topic and section number to which the comment refers. In addition, comments should clearly indicate whether the commenter supports the action being proposed and also clearly indicate the reason(s) for the position. Comments can also include information on alternative management practices, where applicable, that support alternatives to the proposed amendments. Comments should also offer any recommended language change(s) that would be appropriate to the position. Please include relevant information and data to support the position such as scientific, environmental, manufacturing, industry, or impact information, or similar sources. Only relevant material supporting the position should be submitted. All comments received will be posted without change to http://www.regulations.gov.

<u>Document:</u> To access the document and read background documents, or comments received, go to http://www.regulations.gov. Comments submitted in response to this proposed rule will also be available for viewing in person at USDA-AMS, National Organic Program, Room 2642-South Building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m. Eastern Time, Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720-3252.

FOR FURTHER INFORMATION CONTACT: Robert Pooler, Standards Division, National Organic Program. Telephone: (202) 720-3252.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary established the National List within part 205 of the USDA organic regulations (7 CFR 205.600 through 205.607). The National List identifies the synthetic substance allowances and the nonsynthetic substance prohibitions in organic farming. The National List also identifies synthetic and nonsynthetic nonagricultural substances and nonorganic agricultural substances that may be used in organic handling.

The Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501–6522) (OFPA), and § 205.105 of the USDA organic regulations specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic nonagricultural substance used in organic handling be on the National List. Under the authority of OFPA, the National List can be amended by the Secretary based on recommendations presented by the NOSB. Since the final rule establishing the National Organic Program (NOP) became effective on October 21, 2002, USDA's Agricultural Marketing Service (AMS) has published multiple rules amending the National List.

This proposed rule addresses three NOSB recommendations to amend the National List that were submitted to the Secretary on October 26, 2018. Table 1 summarizes the proposed changes to the National List based on these NOSB recommendations.

Table 1. Substances being added to the National List or current listings being amended.

Substance	National List Section	Proposed rule action
Blood meal - made with Sodium citrate	§ 205.601	Add to National List
Natamycin	§ 205.602	Add to National List
Tamarind seed gum	§ 205.606	Add to National List

II. Overview of Proposed Amendments

The following provides an overview of the proposed amendments to designated sections of the National List regulations:

Blood Meal - made with Sodium Citrate

The proposed rule would amend the National List to add blood meal - made with sodium citrate to § 205.601 as a synthetic substance allowed for use in crop production. Table 2 illustrates the proposed listing.

Table 2. Proposed rule action for blood meal using sodium citrate.

Current rule:	N/A
Proposed rule action:	Add blood meal – made with sodium citrate to § 205.601(j).

On July 20, 2016, AMS received a petition¹ to add sodium citrate to the National List as an anticoagulant for spray dried blood products. The addition of sodium citrate prevents the blood from clotting and maintains the blood in a liquid state while it is processed to dried blood meal. In its natural state, blood meal is a nonsynthetic substance that may be used in organic production as a soil amendment.

The NOSB reviewed and considered this petition at its public meeting on October 26, 2018. At the conclusion of meeting, the NOSB recommended to the Secretary to add sodium

https://www.ams.usda.gov/sites/default/files/media/Sodium%20Citrate%20Crops%20Pet.pdf.

¹ Sodium citrate petition:

citrate, for use as an anticoagulant in the production of blood meal, to the National List.² In its recommendation, the NOSB requested that AMS review sodium citrate to determine whether sodium citrate used to process blood meal must be on the National List in order for the resulting blood meal to be allowed in organic crop production.

AMS reviewed the NOSB's sodium citrate recommendation, the sodium citrate petition, and the sodium citrate technical report.³ AMS concurs with the NOSB's determination that sodium citrate is a synthetic substance. Further, AMS concludes that the use of sodium citrate to manufacture blood meal means that blood meal would not qualify as a nonsynthetic substance. AMS also concurs with the NOSB's determination that the construct of the National List does not include processing aids for crop production substances; rather it includes the generic crop production substance. AMS determined that sodium citrate's use as an anticoagulant in the production of blood meal is not included within the production aid categories specified in the OFPA (7 U.S.C. 6517(c)(1)(B)).

Therefore, to address the NOSB's recommendation to allow the use of sodium citrate, AMS is proposing to add blood meal produced with sodium citrate to the National List. This determination is consistent with the current listing for liquid fish products that are pH adjusted with sulfuric, citric, or phosphoric acid and allowed in organic crop production as a plant or soil amendment (§ 205.601(j)(8)). In that case, the addition of a synthetic processing aid, i.e., the specified acids, to a nonsynthetic substance, liquid fish products, was resolved by listing as a synthetic substance liquid fish products that are pH adjusted with the specified acids. The addition of the synthetic substance, sodium citrate, in the processing of blood meal means that

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² NOSB recommendation for sodium citrate:

https://www.ams.usda.gov/sites/default/files/media/CSSodiumCitratePetRecOct2018.pdf.

³ Technical Evaluation Report for sodium citrate (for used in crop production): https://www.ams.usda.gov/sites/default/files/media/SodiumCitrateCropsTR20171218.pdf.

the final product is also synthetic and must be on the National List for use in organic crop production.⁴

In its recommendation to the Secretary, the NOSB stated that there is no concern with using sodium citrate to make dried blood meal and noted that sodium citrate is on the National List in § 205.605(b) as an allowed ingredient for use in organic processing. This proposed rule would amend the National List by adding blood meal made with sodium citrate to § 205.601(j) as a plant or soil amendment.

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.

This proposed rule would add natamycin to § 205.602, Nonsynthetic substances prohibited for use in organic crop production.

Natamycin

The proposed rule would amend the National List to add natamycin to § 205.602. Table 2 illustrates the proposed listing.

Table 3. Proposed rule action for natamycin.

Current rule:	N/A
Proposed rule action:	Add natamycin to § 205.602.

On September 1, 2016, AMS received a petition⁵ to add natamycin as a nonsynthetic substance allowed for use in organic crop production as a post-harvest treatment to control fungal diseases. Natamycin is a naturally occurring compound produced by soil bacteria.

Natamycin is used in agriculture and in food processing for its antifungal properties as either a fungicide or fungistat. These properties are effective over a wide pH range. To enhance review

⁴ Guidance on determining whether a substance is synthetic or non-synthetic is described in document NOP 5033-1, Guidance Decision Tree for Classification of Materials as Synthetic or Nonsynthetic: https://www.ams.usda.gov/sites/default/files/media/NOP-Synthetic-NonSynthetic-DecisionTree.pdf.

Natamycin petition: https://www.ams.usda.gov/sites/default/files/media/Natamycin%20NOP%20Petition%20-%2001%20Sep%2016.pdf.

of this petition, the NOSB solicited a technical report on natamycin.⁶ This report indicates that natamycin is regulated by both the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). Commercial applications of natamycin in crop, livestock, and food production can be grouped into three basic categories: pre- or post-harvest agricultural fungicide; livestock medication; or as a preservative in processed foods. For example, natamycin may be used in mushroom production to control fungal diseases and in post-harvest handling treatment of raw agricultural commodities, such as fruits, to prevent spoilage. Natamycin is also used in animal health for treating ringworm and candidosis in horses and cattle. Natamycin is approved as a preservative in certain processed foods, such as cheese, yogurt, and certain beverages.

The 2016 natamycin petition is the second natamycin petition received and reviewed by the NOSB. In March 2007 the NOSB reviewed a petition on natamycin for use as a nonsynthetic, nonagricultural substance in organic processing and handling, to prevent or delay mold growth in packaged baked goods. After reviewing the 2007 petition, the NOSB considered adding natamycin to the National List in § 205.605(a), Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." At the conclusion of the March 2007 meeting, the NOSB did not recommend adding natamycin to § 205.605(a). Some comments received by the NOSB during the 2007 meeting stated opposition to allowing natamycin in organic handling because the commenters believed that natamycin is an antibiotic, and its use as a preservative would not be compatible with organic standards. In 2007, the NOSB determined natamycin to be a nonsynthetic substance and that its use, as petitioned, was not compatible with organic handling standards.

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⁶ Natamycin Technical Evaluation Report, November 2017: https://www.ams.usda.gov/sites/default/files/media/NatamycinTR20171102.pdf.

At its October 26, 2018, public meeting, the NOSB considered the second natamycin petition as a nonsynthetic substance in organic crop production and received public comment. In its review, the NOSB also considered a November 2, 2017, technical evaluation report on natamycin that described its manufacture, industry uses, regulation, and chemical properties.

After considering the petition, technical report, and public comments, the NOSB determined (1) that natamycin is a nonsynthetic substance and (2) that the use of natamycin as a post-harvest treatment on harvested crops met the OFPA criteria for prohibitions on natural substances because its use could negatively impact human health by increasing fungal resistance to natamycin. As such, its use would not be consistent with organic farming or handling. Therefore, the NOSB recommended adding natamycin to § 205.602 as a nonsynthetic substance prohibited for use in organic crop production.

AMS has reviewed the NOSB recommendation on natamycin and agrees that natamycin meets the OFPA criteria for listing as a prohibited substance in organic crop production. AMS proposes addressing this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend the National List by adding natamycin to § 205.602 as a prohibited nonsysthetic substance. This action would prohibit any use of natamycin in organic crop production, including both pre-harvest and post-harvest treatment. § 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Tamarind seed gum

The proposed rule would amend the National List to add tamarind seed gum as a nonorganic agricultural substance listed in § 205.606 for use in organic handling.

https://www.ams.usda.gov/sites/default/files/media/CSNatamycinPetRecOct2018.pdf.

⁷ NOSB natamycin recommendation:

Table 4. Proposed rule action for tamarind seed gum.

Current rule:	N/A
Proposed rule action:	Add tamarind seed gum to § 205.606.

On February 13, 2017, AMS received a petition⁸ to add tamarind seed gum to the National List in § 205.606 for use in organic handling as a thickener, stabilizer, or gelling agent in processed foods. Tamarind seed gum is a plant polysaccharide (polymer of carbohydrate molecules) derived from the kernel, or endosperm, of seeds of the tamarind tree. Tamarind seed gum is Generally Regarded as Safe (GRAS) for several applications as a food additive—specifically in foods such as cheese, fruit preserves, sauces, and ice cream.

To enhance its review of this petition, the NOSB solicited a technical report⁹ on tamarind seed gum. This report indicated that tamarind seed gum is regulated by the FDA as a GRAS food additive and specifically, as a stabilizer and thickener as defined by 21 CFR 170.3.

At its October 26, 2018, public meeting, the NOSB considered the petition on adding tamarind seed gum to the National List for use in organic handling. As part of its review, the NOSB considered a February 21, 2018, technical report on tamarind seed gum that described its manufacture, industry uses, regulation, and chemical properties. After considering the petition, technical report, and public comments on tamarind seed gum, the NOSB determined that the allowance of non-organic tamarind seed gum for use as an ingredient in organic handling is consistent with the OFPA evaluation criteria for National List substances. The NOSB's evaluation also determined that tamarind seed gum provides different processing characteristics and texture compared to the gums currently on the National List. Subsequently, the NOSB

⁸ Tamarind seed gum petition: https://www.ams.usda.gov/sites/default/files/media/TamGumPetition.pdf.

⁹ Tamarind seed gum technical evaluation report, February 2018: https://www.ams.usda.gov/sites/default/files/media/TamarindSeedGumTR2018221.pdf.

recommended 10 adding tamarind seed gum to § 205.606 as a nonorganically produced agricultural product allowed as ingredients in or on processed products labeled as "organic."

AMS has reviewed the NOSB recommendation on tamarind seed gum and agrees that tamarind seed gum satisfies the OFPA evaluation criteria for an allowed substance on the National List. Subsequently, AMS proposes addressing this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend the National List by adding tamarind seed gum to § 205.606 as a nonorganically produced agricultural product allowed as an ingredient in or on processed products labeled as "organic." This action would require organic handlers who use tamarind seed gum to source an organic form of the ingredient before using any nonorganic source of this ingredient. If the organic form of the ingredient is not commercially available, the nonorganic form may be used. 11

III. Related Documents

On August 9, 2018, a document was published in the Federal Register (83 FR 39376) announcing the fall 2018 NOSB meeting. One purpose of the meeting was to deliberate on recommendations on substances petitioned as amendments to the National List.

IV. Statutory and Regulatory Authority

The OFPA authorizes the Secretary to make amendments to the National List based on recommendations developed by the NOSB. Sections 6518(k) and 6518(n) of the OFPA authorize the NOSB to develop recommendations for submission to the Secretary to amend the National List and establish a process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. Section 205.607

https://www.ams.usda.gov/sites/default/files/media/HSTamarindSeedGumPetRecOct2018.pdf.

11 See 7 CFR 205.606 and 7 CFR 205.2 for definition of "Commercially available."

¹⁰ NOSB recommendation on tamarind seed gum:

of the USDA organic regulations permits any person to petition to add or remove a substance from the National List and directs petitioners to obtain the petition procedures from USDA. The current petition procedures published in the Federal Register (81 FR 12680, March 10, 2016) for amending the National List can be accessed through the NOP Program Handbook on the NOP Web site at https://www.ams.usda.gov/rules-regulations/organic/handbook.

A. Executive Orders 12866 and 13771, and Regulatory Flexibility Act

This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) has exempted from Executive Order 12866. Additionally, because this proposal does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. *See* OMB's Memorandum titled "Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 titled 'Reducing Regulation and Controlling Regulatory Costs'" (February 2, 2017).

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) sets size criteria for each industry described in the North American Industry Classification System (NAICS) to delineate which operations qualify as small businesses. The SBA has classified small agricultural producers that engage in crop and animal production as those with average annual receipts of less than \$750,000.

Handlers are involved in a broad spectrum of food production activities and fall into various categories in the NAICS Food Manufacturing sector. The small business thresholds for food manufacturing operations are based on the number of employees and range from 500 to 1,250 employees, depending on the specific type of manufacturing. Certifying agents fall under the NAICS subsector, "All other professional, scientific and technical services." For this category, the small business threshold is average annual receipts of less than \$15 million.

AMS has considered the economic impact of this proposed rulemaking on small agricultural entities. Data collected by the USDA National Agricultural Statistics Service (NASS) and the NOP indicate most of the certified organic production operations in the United States would be considered small entities. According to the 2017 Census of Agriculture, 18,166 organic farms in the United States reported sales of organic products and total farmgate sales in excess of \$7.2 billion. Based on that data, organic sales average \$400,000 per farm. Assuming a normal distribution of producers, we expect that most of these producers would fall under the \$750,000 sales threshold to qualify as a small business.

According to the NOP's Organic Integrity Database, there are 18,105 organic handlers that are certified under the USDA organic regulations (10,184 of these handlers are based in the U.S). The Organic Trade Association's 2018 Organic Industry Survey has information about employment trends among organic manufacturers. The reported data are stratified into three groups by the number of employees per company: less than 5; 5 to 49; and 50 plus. These data are representative of the organic manufacturing sector and the lower bound (50) of the range for the larger manufacturers is significantly smaller than the SBA's small business thresholds (500).

¹² U.S. Department of Agriculture, National Agricultural Statistics Service. 2017 Census of Agriculture. https://www.nass.usda.gov/Publications/AgCensus/2017/Full Report/Volume 1, Chapter 1 US/. The number of organic farms includes both certified and exempt farms.

¹³ Organic Integrity Database: https://organic.ams.usda.gov/Integrity/. Accessed on June 7, 2019.

to 1,250). Therefore, AMS expects that most organic handlers would qualify as small businesses.

The USDA has 78 accredited certifying agents who provide organic certification services to producers and handlers. The certifying agent that reports the most certified operations, nearly 3,500, would need to charge approximately \$4,200 in certification fees in order to exceed the SBA's small business threshold of \$15 million. The costs for certification generally range from \$500 to \$3,500, depending on the complexity of the operation. Therefore, AMS expects that most of the accredited certifying agents would qualify as small entities under the SBA criteria.

The economic impact on entities affected by this rule would not be significant. The effect of this rule, if implemented as final, would be to allow the use of two additional substances in organic crop production and organic handling. Adding two substances to the National List would increase regulatory flexibility and would give small entities more tools to use in day-to-day operations. This action would also prohibit the use of natamycin in organic crop production due to its possible impact on human health. AMS reviewed comments submitted to the NOSB indicating that there is little to no use of natamycin currently in organic crop production.

Therefore, AMS concludes that the economic impact of this addition, if any, would be minimal because there are other practices and substances that provide effective fungal control in organic crop production. Accordingly, USDA certifies that this rule would not have a significant economic impact on a substantial number of small entities.

B. Executive Order 12988.

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This proposed rule is not intended to have a retroactive effect. Accordingly, to prevent

duplicative regulation, states and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or state officials who want to become certifying agents of organic farms or handling operations. A governing state official would have to apply to USDA to be accredited as a certifying agent, as described in section 6514(b) of the OFPA. States are also preempted under sections 6503 through 6507 of the OFPA from creating certification programs to certify organic farms or handling operations unless the state programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 6507(b)(2) of the OFPA, a state organic certification program that has been approved by the Secretary may, under certain circumstances, contain additional requirements for the production and handling of agricultural products organically produced in the state and for the certification of organic farm and handling operations located within the state. Such additional requirements must (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

In addition, pursuant to section 6519(c)(6) of the OFPA, this proposed rule would not supersede or alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601–624), the Poultry Products Inspection Act (21 U.S.C. 451–471), or the Egg Products Inspection Act (21 U.S.C. 1031–1056), concerning meat, poultry, and egg products, respectively, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

C. Paperwork Reduction Act.

No additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of

1995, 44 U.S.C. 3501, Chapter 35.

D. Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive

Order 13175, Consultation and Coordination with Indian Tribal Governments. The review

reveals that this regulation will not have substantial and direct effects on tribal governments and

will not have significant tribal implications.

F. General Notice of Public Rulemaking.

This proposed rule reflects recommendations submitted by the NOSB to the Secretary to

add two substances to the National List and notify organic producers and certifying agents of

AMS's decision not to add sodium citrate to the National List. A 60-day period for interested

persons to comment on this rule is provided.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports,

Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements,

Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205 is proposed to be amended as

follows:

PART 205—NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501–6522.

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2. Amend § 205.601 by redesignating paragraphs (j)(2) through (11) as paragraphs (j)(3)
through (12) and adding new paragraph (j)(2) to read as follows:
§ 205.601 Synthetic substances allowed for use in organic crop production.
* * * * *
(j) * * *
(2) Blood meal – made with sodium citrate.
* * * * *
3. Amend § 205.602 by redesignating paragraphs (e) through (j) as paragraphs (f) through (k)
and adding new paragraph (e) to read as follows:
§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.
* * * * *
(e) Natamycin.
* * * * *
4. Amend § 205.606 by redesignating paragraphs (s) through (w) as paragraphs (t) through (x)
and adding new paragraph (s) to read as follows:
§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on
processed products labeled as "organic."

(s) Tamarind seed gum.
* * * * *
Dated: October 11, 2019
Bruce Summers Administrator Agricultural Marketing Service

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